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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/465,276	12/16/99	BAVARI S	003/175/SAP

HM12/0607
U S ARMY MEDICAL RESEARCH AND
MATERIEL COMMAND
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EXAMINER	
ZEMAN, R	
ART UNIT	PAPER NUMBER
1645	5

DATE MAILED: 06/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/465,276	Bavari et al.
Examiner	**Art Unit**
Robert A. Zeman	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 16, 1999* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-28* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4, 18 and 21 (in part), drawn to monoclonal antibody 4A2-2, the hybridoma cell line producing said antibody, a pharmaceutical composition comprising said composition and a kit comprising said antibody, classified in class 530, subclass 388.4.

II. Claims 2, 5, 19 and 21 (in part), drawn to monoclonal antibody 6B2-2, the hybridoma cell line producing said antibody, a pharmaceutical composition comprising said composition and a kit comprising said antibody, classified in class 530, subclass 388.4.

III. Claims 3, 6, 20 and 21 (in part), drawn to monoclonal antibody 6C2-4, the hybridoma cell line producing said antibody, a pharmaceutical composition comprising said composition and a kit comprising said antibody, classified in class 530, subclass 388.4.

IV. Claim 7, drawn to a monoclonal antibody that binds to amino acids 1150-1287 of BoNT/A, classified in class 530, subclass 388.4.

V. Claim 8, drawn to a monoclonal antibody that binds to amino acids 1157-1181 of BoNT/A, classified in class 530, subclass 388.4.

VI. Claim 9, drawn to a monoclonal antibody that binds to amino acids 1230-1253 of BoNT/A, classified in class 530, subclass 388.4.

VII. Claim 10, drawn to a monoclonal antibody that binds to amino acids 1157-1253 of BoNT/A, classified in class 530, subclass 388.4.

VIII. Claim 11, drawn to DNA encoding a binding domain of monoclonal antibody 4A2-2, classified in class 536, subclass 23.7.

IX. Claim 12, drawn to DNA encoding a binding domain of monoclonal antibody 6B2-2, classified in class 536, subclass 23.7.

X. Claim 13, drawn to DNA encoding a binding domain of monoclonal antibody 6C2-4, classified in class 536, subclass 23.7.

XI. Claims 14-16, drawn to methods of detecting the BoNT protein, classified in class 435, subclass 7.32.

XII. Claim 17, drawn to a method of treating BoNT intoxication, classified in class 424, subclass 167.1.

XIII. Claims 22-26, drawn to BoNT peptide vaccines, classified in class 530, subclass 300.

XIV. Claims 27-28, drawn to methods of capturing/isolating the BoNT protein, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-X and XIII are separate and distinct from each other as they each comprise completely differing molecular, biochemical and immunological entities having differing properties and uses. Each invention is drawn to a distinct monoclonal antibody.

Inventions I-VII are each related to invention XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the monoclonal antibodies of Invention I-VII can be used in protein purification methods.

Inventions I-VII are each related to invention XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the monoclonal antibodies of Invention I-VII can be used in protein purification methods.

Inventions I-VII are each related to invention XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the monoclonal antibodies of Invention I-VII can be used in treatment protocols.

Inventions VIII-X and XIII are each separate and distinct from Inventions XI, XII and XIV as the DNA of Inventions VIII-X and the peptide vaccines of Invention XIII cannot be used in the methods of Invention XI, XII or XIV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

June 5, 2001